

DEC 29 1995

Mr. Harris Schnall
President
J.B. Harris, Inc.
4324 Regency Drive
Glenview, Illinois 60026

Dear Mr. Schnall:

This is in response to your letter of September 28, 1995 making a submission to the Food and Drug Administration (FDA) pursuant to section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the act). Your submission states that you are making the following statement in the labeling of the product "Sambucol™":

Sambucol™ is a safe and effective virus control.
Sambucol™ stops viruses in the throat before they spread.

We would point out that section 403(r)(6) of the act makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of disease. The statement that you are making for "Sambucol™," however, suggests that this product is in fact intended for one of these purposes in that it claims to be a safe and effective virus control and stops viruses in the throat before they spread. Therefore, this claim does not qualify as a section 403(r)(6) claim. Use of this claim on the label or in the labeling of your product is likely to subject it to regulation under the drug provisions of the act.

If you intend to make claims of this nature, you should immediately contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

Sincerely yours,

Elizabeth A. Yetley, Ph.D., R.D.
Director
Office of Special Nutritionals
Center for Food Safety
and Applied Nutrition

975-0163

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J. B. HARRIS INC.

4324 Regency Drive
Glenview, IL 60025

September 28, 1995

Victor Fratelli, PhD.
Office of Special Nutritionals
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street
HFS-455
Washington, DC 20204

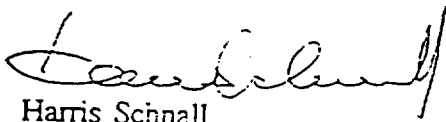
Dear Dr. Fratelli,

Notice is hereby given pursuant to the requirements to Section 403(r)(6) (21 U.S.C. 343(r)(6)) of the Federal Food, Drug, and Cosmetic Act of statements of nutritional support which have been made on the label and in the labeling in connection with the marketing of the dietary supplement Sambucol™. Sambucol™ was first marketed with these statements of nutritional support on September 16, 1995. The statements of nutritional support are as follows:

- Sambucol™ is a safe and effective virus control.
- Sambucol™ stops viruses in the throat before they spread.

Very truly yours,

J. B. HARRIS, INC.


Harris Schnall
President

HS:ng

cc: Richard J. Littner
Nutrinfo Corporation

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